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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/709,318 | 04/28/2004 | Siddhartha Panda | FIS920040032US1 | 3317 |
| 29371 | 7590 | 12/13/2005 | EXAMINER | |
| CANTOR COLBURN LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002 | | | WOOLWINE, SAMUEL C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/709,318 | PANDA ET AL. |
| | Examiner | Art Unit |
| | Samuel Woolwine | 1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
 - 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 12-16 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/28/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to methods of nucleic acid analysis, classified in class 435, subclass 6.
 - II. Claims 12-16, drawn to a biochemical/molecular biological apparatus, classified in class 435, subclass 283.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the apparatus of Group II could be used to carry out the methods of Group I, but could also be used as a general heating device, for example, as a means of regulating the water temperature in an aquarium.

3. In addition, a search of the prior art would be different for Groups I and II. Because the apparatus could be used for other purposes than the methods of Group I, a search based on classification would include a search not only of class 435/283.1, but would also need to include, for example class 432 (Heating). In addition, a text-based search would be different because a search of Group II would require a broad search based on infrared heating, since any apparatus meeting the structural limitations of the

claims of Group II would be anticipatory, regardless of intended use. Therefore, a search for both Groups would constitute an undue burden on the resources of the Office.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Lisa Jaklitsch on 11/30/05 a provisional election was made without traverse to prosecute the invention of Group II, claims 12-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a**

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Conia et al (US Pat 5,972,667).

3. Regarding claim 12, Conia teaches: *A temperature cycling apparatus, comprising: a processing chamber; (see, e.g. figure 1 and column 6 lines 35-41) an infrared (IR) heating source, (see column 3, lines 20-30) said infrared heating source configured to generate energy a first infrared wavelength so as to generate a first desired temperature for a first duration and produce a first desired reaction within a sample placed in said processing chamber; (see column 5 line 67 through column 6 line 10, and see claim 10) and said infrared (IR) heating source is further configured to generate energy at a second infrared wavelength so as to generate a second desired temperature for a second duration and produce a second desired reaction within the sample (see column 5 line 67 through column 6 line 10, and see claim 10). With particular regard as to selecting an infrared wavelength so as to generate a desired temperature and generating multiple desired temperatures, note Conia teaches: "The systems and methods described in the present invention accomplish laser-generated incremental temperature elevations...which is a function of the laser beam intensity, wavelength, profile and distributed photon intensity, which can be controlled...to favor one, several or all phases of the polymerase chain reaction" (column 5, line 67 through*

column 6, line 10, emphasis added). Conia also teaches several lasers emitting different wavelengths in the infrared range (column 3, lines 50-60).

4. Regarding claim 13, Conia teaches: *The temperature cycling apparatus of claim 12, wherein said infrared (IR) heating source further is configured to generate energy at a third infrared wavelength so as to generate a third desired temperature for a third duration and produce a third desired reaction within the sample.* See column 3, lines 20-30, and see column 5, line 67 through column 6, line 10, and see claim 10. See also figure 1 and column 6, lines 35-41. With particular regard as to selecting an infrared wavelength so as to generate a desired temperature and generating multiple desired temperatures, note Conia teaches: "The systems and methods described in the present invention accomplish laser-generated incremental temperature elevations...which is a function of the laser beam intensity, wavelength, profile and distributed photon intensity, which can be controlled...to favor one, several or all phases of the polymerase chain reaction" (column 5, line 67 through column 6, line 10, emphasis added).

5. Regarding claim 14, Conia teaches: *The temperature cycling apparatus of claim 13, wherein: said first desired temperature corresponds to a denaturing step for a polymerase chain reaction (PCR) process; said second desired temperature corresponds to an annealing step for said PCR process; and said third desired temperature corresponds to an extending step for said PCR process.* See column 3, lines 20-30, and see column 5, line 67 through column 6, line 10, and see claim 10. See also figure 1 and column 6, lines 35-41. With particular regard as to selecting an infrared wavelength so as to generate a desired temperature and generating multiple

desired temperatures, note Conia teaches: "The systems and methods described in the present invention accomplish laser-generated incremental temperature elevations...which is a function of the laser beam intensity, wavelength, profile and distributed photon intensity, which can be controlled...to favor one, several or all phases of the polymerase chain reaction" (column 5, line 67 through column 6, line 10, emphasis added).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conia et al (US Pat 5,972,667) in view of Oh et al (Pub No US 2003/0092172 A1).

8. Claims 15 and 16 depend from claims 12-14. Regarding claim 12, Conia teaches: *A temperature cycling apparatus, comprising: a processing chamber; (see, e.g. figure 1 and column 6 lines 35-41) an infrared (IR) heating source, (see column 3, lines 20-30) said infrared heating source configured to generate energy a first infrared wavelength so as to generate a first desired temperature for a first duration and produce a first desired reaction within a sample placed in said processing chamber; (see column 5 line 67 through column 6 line 10, and see claim 10) and said infrared (IR) heating source is further configured to generate energy at a second infrared wavelength so as*

to generate a second desired temperature for a second duration and produce a second desired reaction within the sample (see column 5 line 67 through column 6 line 10, and see claim 10).

9. Conia also teaches claim 13: *The temperature cycling apparatus of claim 12, wherein said infrared (IR) heating source further is configured to generate energy at a third infrared wavelength so as to generate a third desired temperature for a third duration and produce a third desired reaction within the sample.* See column 3, lines 20-30, and see column 5, line 67 through column 6, line 10, and see claim 10.

10. Conia further teaches claim 14: *The temperature cycling apparatus of claim 13, wherein: said first desired temperature corresponds to a denaturing step for a polymerase chain reaction (PCR) process; said second desired temperature corresponds to an annealing step for said PCR process; and said third desired temperature corresponds to an extending step for said PCR process.* See column 3, lines 20-30, and see column 5, line 67 through column 6, line 10, and see claim 10. See also figure 1 and column 6, lines 35-41. With particular regard as to selecting an infrared wavelength so as to generate a desired temperature and generating multiple desired temperatures, note Conia teaches: "The systems and methods described in the present invention accomplish laser-generated incremental temperature elevations...which is a function of the laser beam intensity, wavelength, profile and distributed photon intensity, which can be controlled...to favor one, several or all phases of the polymerase chain reaction" (column 5, line 67 through column 6, line 10,

emphasis added). Conia also teaches several lasers emitting different wavelengths in the infrared range (column 3, lines 50-60).

11. With regard to claims 15 and 16, Conia does not teach an apparatus further comprising a first, second and third chamber, each said chamber being of a different temperature and having a different infrared wavelength. Oh teaches an apparatus comprising a first, second and third chambers, each maintained at separate temperatures (see for example figures 9-11 and page 2, paragraph [0030]). Regarding claim 16, Oh teaches a conveyer comprising a system of channels and valves connecting the chambers and pneumatic air pressure providing the driving force to transport the sample from one chamber to the next (see page 2, paragraph [0034]). Oh teaches the use of infrared energy as a means of providing an appropriate temperature in the reaction chamber (see page 3, paragraph [0046] and claim 17). Oh does not teach the use of infrared energy of different wavelengths. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to combine the teachings of Conia for using different infrared wavelengths to control the temperature of the sample in the reaction chamber with the use of separate sample chambers connected by the conveyer system as taught by Oh. Conia clearly teaches achieving a target temperature by controlling the wavelength of the infrared energy source: "The systems and methods described in the present invention accomplish laser-generated incremental temperature elevations...which is a function of the laser beam intensity, wavelength, profile and distributed photon intensity, which can be controlled...to favor one, several or all phases of the polymerase chain

reaction" (column 5, line 67 through column 6, line 10, emphasis added). Conia also clearly teaches the use of different lasers producing different wavelengths of infrared energy (see column 3, lines 45-59) and provides motivation to use lasers (and thus defined wavelengths) for use in microscopic devices: "A laser beam focused by the objective lens of a microscope can be used to illuminate or to transfer energy to a very small part of a microscopic target specimen" (column 4, lines 48-51). This motivation to use lasers (and thus defined wavelengths) harmonizes with the express teaching of Oh to use his invention in a microchip or "lab on a chip" format for PCR (page 5, paragraph [0071]). Oh provides motivation to use discrete chambers maintained at different temperatures for the different stages of PCR because in his system, "there is no need for any circuits for cooling or cooling system" (page 5, paragraph [0068]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SCW

JEFFREY FREDMAN
PRIMARY EXAMINER
12/3/05